

ቀን 3 0 DEC 2022 ቁጥር Ref. No. EPSA / 06/561/01

To: All participants of tender with Ref. No. ICB/EPSA6/RDF-Routine/MD/10/22

## Subject: Amendment and Clarification on tender with ref. No. ICB/EPSA6/RDF-Routine/MD/10/22

Dear Sirs,

Reference is made to the above captioned tender. We hereby clarify that:-

- A. For Item No.10 (IV Stand); the material type for the hook and pole is medical grade stainless steel and plastic for the base.
- B. For Item No.11 (Monitor Patient); as clearly indicated on the bidding document the device needs both wall mounting kit and carts with 12 lead ECG electrodes.
- C. For Item No.30 (Tonometer); The requested device is hand held non-contact tonometer.
- D. For Item No.45 (Resuscitator Adult, Pediatric & Infant); The requested resuscitator is kit of three (Adult, Pediatric and Infant)
- E. The requested IEC-60601 is only applicable for the medical devices which require electricity to operate.
- F. Item No. 44 (Echocardiography Machine); is the newly added medical device to this tender and the technical specification is attached. The evaluation requirement will be as per the tender captioned above.
- G. For Item No. 42 (Laundry Machine); The required product certificate is as per the directive of 426/2016/full product quality assurance from SRA Region.
- H. The bidders must submit softcopy of their bidding document starting from the 1<sup>st</sup> front page to the last back page during bid submission.

We kindly inform you that the tender closing/opening date and time is postponed to January 16, 2023 GC, 2:00PM/2:30PM.

With Best Regards

Enc. 06 Pages

CC:

Deputy Director General (Inbound Logistics)

And Supply

Output

Deputy Director General (Inbound Logistics)

Medical Equipment Tender Management Team

Archive EPSS

S.No	Item Name	Unit	Qty
44	1. Generic Name: Echocardiography machine	Each	1
	Bidder:		
	Manufacturer Name:		
	Manufacturer Country of Origin:		
	Quoted Product Model:		
	Product Certificate from SRA Region:		
	Country of Origin		
	EFDA Product Certificate:		
	2. GMDN/UMDN Code/Name::		
	3. Clinical Purpose/Description:		
	2. GMDN/UMDN Code/ Name:		
	3. Description/Clinical Purpose		
	Echocardiography machines diagnostic Equipment that uses high frequency sound waves to tests internal heart structures and blood flow inside cardiac structures.		-
	4.Technical Specification:		
	Latest generation, highest end & technologically advanced Digital Live 3D Echocardiography system for Transthoracic adult, pediatric cardiac applications.		`
16	Should have 256 gray shades for sharp contrast resolutions		<u> </u>
	Multi-dimensional Beam former for generating two images simultaneously and selectively retrieves and mixes the components together for superior contrast resolution		
	Adult Cardiac and Vascular Probe with wide band transducers without frequency selection for higher sensitivity of response over a broader frequency range of operation.		
	Operating Mode: Spectral Doppler, 3D, 2D, M-Mode, Steerable PW/CW Doppler, Colour Doppler and High Definition Colour flow.		
	Electronic Phased array Color Doppler system with Minimum 512 Electronic independent channels		
	Harmonic imaging capability in Adult Cardiac, Pediatric Cardiac and linear Probe		
	Gain control in two dimensions for additional level of flexibility to image quality control.		
	Real time high frequency 2D for higher resolution and low frequency Doppler for higher sensitivity in all probes		
	Steerable PW/CW in Phased Array probes.		
	High definition acoustic zoom for enlarging sections of 2D and Color flow images with more acoustic information for greater clarity and detail while maintaining an optimal frame rate.		
	High Definition Color flow with capability of automatically picking up color flow as a function of focal depth		
	Monitor 17" or more, high resolution color Monitor with articulated arm		



П			Qty
	Four Castor with Break		
	Height adjustable control panel and integrated audio speaker		
	Tilt and Swivel monitor be able to view in all angles and all light conditions.		wit.
	System capable of live 3D imaging in transesophageal applications		
	System with a minimum 100,000 or more digitally scalable channels for simultaneous formation, acquisition and processing of multiple ultrasound beams and has a system architecture to process an entire bandwidth of frequencies from 2MHz to 15 MHz.		
	System have a dynamic range of minimum 200 dB so that variety of patient sizes can be handled without compromise.		
	System be capable of supporting live 3D matrix transducer with Separate live 3D Matrix Transducers for both adult and pediatric applications.		
	The footprint size of the pediatric matrix transducer lesser than the adult matrix transducer and frequency of the paediatric matrix transducer be higher.		
	Capable of scanning depth ≥20 cm		
	System with extremely high Resolution 2D Imaging, Colour Flow Imaging, M Mode, PW Doppler, CW Doppler, Duplex & Triplex Modes.		
	advanced Tissue Doppler imaging with high frame rate acquisition of more than 500 frames per second.		
-	System have at least four imaging universal active probe ports with electronic switching facility from keyboard without probe adaptor.		
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	on-board workstation for storage and review of all exams, 2D, 3D Images and loops		
	System have DICOM print and store service classes with support for modality, work list, perform procedure set up, storage commitment		
	System have inbuilt Image Management facility for direct storage of Images and loops in the Hard Disk Drive and also thumbnail review to view & edit Images, loops and also reports.		
	System have storage facility of images, loops in the hard disk drive of 1 TB or more.		
	System be able to transfer Images & clips to CD & DVD media.		
	Color Doppler System with all application packages		
	Adult Echo Transducer (crystal) with frequency ranging from 1-5 MHz.		
	Pediatric Echo Transducer with frequency ranging from 3-8 MHz.		
	Neonatal Echo Transducer with frequency ranging from 4-10 MHz		
	Linear Array Transducer with frequency ranging from 3-12 MHz for vascular applications.	-	

S.No	Item Name	Unit	Qty
	Convex Array Matrix Transducer for adult live 3D with frequency ranging from 1-5 MHz.		
	Live 3D Echo Matrix Transducer for Adult live 3D with frequency ranging from 1-5 MHz.		
	TEE transducer for Adult (Live 3D/4D) & Pediatric (2D) Echocardiography - 01 for each		
	Integrated stress echo facility to perform stress echo exams.		
	Contrast Harmonic Imaging		
F.	Latest PC (off-line licensed workstation) with licensed software for analyzing and quantification of 2D and 3D data sets, CD writer with Image Management Software and colour laser Printer.		
	PC with a flat panel 17 inch or more display monitor.		
	Advanced tissue Harmonic Imaging.		
	color flow imaging.		
	color Tissue Doppler Imaging.		
	gain control in Axial Plane.		
	triple imaging possibility on the system.		
	PW/CW Doppler facility in all imaging phased array sector		
	Color Flow Imaging for		
	a) Increased lateral & spatial resolution.		
	b) Detection of even subtle areas of turbulence, displaying a more physiological blood flow appearance without loss of frame rate.		
	Tissue Colorization (B-Color) for improved contrast resolution		
	Application software for Adult, Pediatric, Fetal and Peripheral Vascular and Transesophageal applications. (All application package built into the system)		
	Cine loop memory- more than 120MB of memory.		
	a. High Frame rate review for better clarity of playback images study in slow motion.		
	b. Quad loop with memory for pre and post image comparison of any procedure.		
	c. Memory- 256 frames or more in quad loop. M Mode & Doppler Scroll Memory - 40 seconds or more.		
	d. Frame grabber facility for post analysis.		
	Latest generation Electronic Phased array Colour Doppler system with Minimum 50,000 digital processing channels with live 3D imaging.		
	Adult & Pediatric Trans thoracic Cardiac, TEE (Adult & Paediatric) and Vascular Probes be latest generation wide band transducers.		
	DVD/CD writer, flash memory and USB connector		
	Dedicated integrated dynamic stress echo package for flexible user defined protocols with stacked sub loops facility and contrast stress protocol usable for stress echocardiography.		
	Tissue movement colorization with quantification possibility for IHD/CAD/Heart Failure patients.		
	Colour Map resolution		

S.No	Item Name	Unit	Qty
	Facility for high definition digital acquisition, review and editing of complete patient studies.		
	Colour Doppler System with all application packages Quad loop for serial studies with High frame rate review.		
	Harmonic imaging capability in all modes. Integrated Stress Echo Package Digital Storage and Retrieval		
	Harmonic Imaging - System have following modes in harmonic with separate setting for:		
	a. Tissue Harmonic.		
	b. Contrast Harmonic		
	c. Harmonic Angio.		
	d. Quantification of harmonics imaging		
	Harmonic imaging capability in Adult Cardiac, Pediatric Cardiac and linear Probe		
	Colour Flow Imaging for:		
	a. Increased lateral & spatial resolution.	4	
	b. Detection of even subtle areas of turbulence, displaying a more physiological blood flow appearance without loss of frame rate.		
a .	c. Colour flow with capability of automatically picking up colour flow as a function of focal depth		a
	Cine loop memory equivalent cineloop memory in frames/sec.		
	a. High Frame rate review for better clarity of playback images study in slow motion.	5	
	b. Quad loop with memory for pre and post image comparison of any procedure.		
	c. Memory- 256 frames or more in quad loop. M Mode & Doppler Scroll Memory 40 seconds or more.		
	d. Frame grabber facility for post analysis.		
	Various maps for pre and post processing.		
	Various maps for pre and post processing.		
	ECG trigger facility with ECG signal trapping cables and electrodes		
	User defined system and application presets for multi-user department.		
	Minimum 5 GB optical disc drive for image storage and retrieval		
7	Dedicated integrated dynamic stress echo package for flexible user defined protocols with stacked sub loops facility and contrast stress protocol.		
	Tissue movement colorization with quantification possibility for IHD/CAD patients.		
	Color Map resolution up to 128 levels.		
	Facility of Real time perfusion studies		
	CD Writer with calculation facility on playback.		
	Color Video Printer.		
	B/W Thermal Printer.		



S.No	Item Name	Unit	Qty
	Colour M-Mode		
	Color Doppler System with all application packages		
	Quad loop for serial studies with High frame rate review.		
	10x Ultrasound Gel of ≤9 OZ, Squeeze bottle		
	DVD/CD Recorder with 100 CDs and 100 DVDs		
í	Integrated B/W Thermal Printer -01		
	Colour Print Paper- 500 sheets		
	Set of ECG Cable and electrode - 02 of each		
	5 Accessories/Consumables/Spare part and other component		
	With all standared and complete Accessories/Consumables startup kit	-	
	UPS system with minimum 2Hr back-up		
	Voltage stabilizer of appropriate rating		
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).		
	6.Operating Environment:		
	Operating Temperature: +10°C to +30°C		
	Relative Humidity: <85%		
(2)	7. Utility Requirements:		
	Electrical Power Supply: 100 - 230VAC		
	8. Standards and Safety Requirements:		
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility		
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)		
	Should have safety certificate from a competent authority CE / FDA & other		
·	9. Installation, Training and Commissioning		
	The supplier must be provide installation, and commissioning of the device		
	The supplier must be provide technical and end user training for Two weeks on site.		
	10. Warranty and After Sale service		
	The supplier must be provide minimum of Two year basic warranty including labour and spare part from the date of installation.		3
	After basic warranty the supplier must be provide Five years maintenance contract period with price break down along with quotation.	1	
	11. Documentation		-
	User, technical and maintenance manual must be supplied in English along with quotation and devices/machines.		
	12. Packaging and Labeling		



S.No	Item Name	Unit	Qty
	Packing of all the goods must be clearly marked and securely packed. Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.		
	Additional packing and labeling requirements should bear in each package		
-	Federal Democratic Republic of Ethiopia Pharmaceuticals Fund and Supply Agency (PFSA)		
	Tender and Purchase Order No.		
	UMDNS Name and Model of the product		
	PO Box 25-11-276-32-65		
	Tel: +251-11-276-32-65		
	Fax: +251-11-275-25-55		
	Addis Ababa, Ethiopia		